[Docket No. 2633]

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 19-2875 (RMB/SAK) **OPINION**

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RENÉE MARIE BUMB, Chief United States District Judge:

This multi-district litigation ("MDL") has been pending for six long years. It involves the manufacture and sale of allegedly adulterated high blood pressure medication. Hundreds of motions and requests have required the Court's attention. Now before the Court is the Motion to Exclude the Opinions of Dr. Rena Conti filed by the TPP Trial Defendants[1] [Docket No. 2633]. Having considered the parties' submissions[2] and having had the benefit of extensive oral argument and a *Daubert* hearing, the Court now resolves the Motion and provides the parties with much needed guidance on next steps in the litigation. For the reasons set forth herein, the Motion will be **GRANTED**.

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[1] The "TPP Trial Defendants" include Zhejiang Huahai Pharmaceuticals Co., Ltd., located in China, and its U.S. subsidiaries: Huahai U.S. Inc.; Prinston Pharmaceutical Inc. d/b/a Solco Healthcare LLC; and Solco Healthcare U.S. (collectively, "ZHP"); Teva Pharmaceuticals USA, Inc.; Teva Pharmaceutical Industries Ltd.; Actavis LLC; and Actavis Pharma, Inc. (collectively, "Teva"); Torrent Pharmaceuticals Ltd., located in India, and its U.S. subsidiary, Torrent Pharma, Inc. (together, "Torrent"). For simplicity, the Court largely refers to the TPP Trial Defendants as the "Defendants" in this Opinion.

The "Plaintiffs" or "TPP Trial Plaintiffs" refer to MSP Recovery Claims, Series LLC ("MSP") as class representative of numerous Third-Party Payors ("TPPs"). MSP is the assignee of economic loss claims from two TPP assignors, SummaCare and Emblem Health.

[2] Defendants filed a brief in support of their Motion to exclude Conti's expert testimony on various grounds [Defs.' Br. (Docket No. 2633-1)]. Plaintiffs have opposed [Pls.' Opp'n (Docket No. 2662)] and Defendants have submitted a reply brief in further support of the Motion [Defs.' Reply (Docket No. 2676)].

I. FACTUAL AND PROCEDURAL BACKGROUND

This MDL as a whole is sprawling, encompassing dozens of classes of plaintiffs, upstream and downstream defendants, and multiple theories of liability covering both economic losses and personal injury. Valsartan is the generic name of the now off-patent anti-hypertensive drug Diovan®. It is also used in a combination heart failure drug called Exforge®. At its core, the litigation involves the alleged contamination with nitrosamines of certain Valsartan-containing drugs manufactured, distributed, or sold by Defendants (the "VCDs") from January 1, 2012 through the recalls of those drugs in the summer of 2018.[3]

This Opinion concerns only a subset of claims, plaintiffs, and defendants, set forth in the Third Amended Consolidated Economic Loss Class Action Complaint ["Compl." (Docket No. 1708)], that were being readied for a bellwether trial that has been referred to as the "TPP Trial." Notably, the TPP Trial involves only economic loss claims – sounding in breach of express warranty, state consumer protection laws, and common law fraud – brought by TPPs. It does not involve individual consumer plaintiffs or personal injury claims.

[3] The nitrosamines alleged to have been present in the VCDs include N-Nitrosodimethylamine ("NDMA") and N-Nitrosodiethylamine ("NDEA"). Nitrosamines are classified as probable genotoxic carcinogens by the U.S. Food and Drug Administration ("FDA").

For years the parties litigated their disputes regarding the TPP Trial before the Honorable Robert B. Kugler.[4] Then, a year ago, upon Judge Kugler's retirement and the reassignment of the case to this Court, the parties attempted to re-litigate, if not the case, many of the issues. Generally speaking, the Court declined and proceeded to reschedule the TPP Trial. Thereafter, one thing quickly became clear to this Court: there was a vast disconnect between the parties as to what the upcoming TPP Trial would entail. Any trial would be a farrago of undeveloped claims. As a result, the Court delayed the trial.

In particular, the primary source of contention involves Plaintiffs' theory of damages for its breach of express warranty cause of action. Generally speaking, Plaintiffs press the following syllogism: Because the VCDs contained nitrosamines,

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[4] Judge Kugler issued several thorough Opinions in this case that the Court references herein using the following abbreviations:

"MTD 2 Op." refers to *In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig.*, No. MDL 2875 (RBK/JS), 2021 WL 100204 (D.N.J. Jan. 12, 2021).

"MTD 3 Op." refers to *In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig.*, No. MDL 2875 (RBK-JS), 2021 WL 222776 (D.N.J. Jan. 22, 2021).

"Class Cert. Op." refers to *In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig.*, No. 19-2875 (RBK/SAK), 2023 WL 1818922 (D.N.J. Feb. 8, 2023).

"Decert. Op." refers to *In re Valsartan, Losartan & Irbesartan Multi-Dist. Litig.*, No. 19-MD-2875 (RBK/SAK), 2024 WL 776757 (D.N.J. Feb. 26, 2024).

"SJ Op." refers to *In re Valsartan, Losartan & Irbesartan Multi-Dist. Litig.*, No. 19-MD-2875 (RBK/SAK), 2024 WL 1286347 (D.N.J. Mar. 26, 2024).

i.e., known carcinogens, they were adulterated. Because they were adulterated, they should not have been sold. Because they should not have been sold, they were worthless. Because they were worthless, Plaintiffs are entitled to a full refund. To support this syllogism, Plaintiffs rely heavily on the opinion of their damages expert, Professor Rena Conti, Ph.D.

This is not the first time the Court has had the opportunity to assess Conti's testimony. At the class certification stage, Plaintiffs proffered Conti's testimony to support the "fact of economic damage" and their class-wide damages calculations. [Pls.' Class Cert. Conti Opp'n at 1 (Docket No. 2086).] Defendants moved to exclude her expert testimony on various grounds. Most relevant to the Court's determination in this Opinion, Defendants argued that Conti's methodology was unreliable because she unjustifiably conflated price and value, and she ignored real-world evidence that the VCDs provided substantial benefits to both consumers and the TPPs. [Defs.' Class Cert. Conti Br. at 8–13 (Docket No. 2040-1).] Additionally, Defendants contended that the concept of a "legitimate" supply curve, which Conti used to opine that the VCDs were worthless, was based on policy rather than economics. [*Id.* at 13–14.] Defendants also challenged the fit of Conti's testimony because she focused solely on point-of-sale payments and did not consider any offsets. [*Id.* at 16–18.] Judge Kugler rejected Defendants' arguments and found that Conti was qualified to opine on economic loss, recognizing, however, that at this early stage, "the methodology of an expert need not be perfect or even legally correct." Class Cert. Op. at *49, *51.

Extensive discovery, motion practice, and trial preparation were then undertaken. The TPP Trial was set to commence on March 18, 2024. In February 2024, in advance of the upcoming TPP Trial, the parties filed numerous motions, including a motion to decertify the TPP Trial subclasses [Docket No. 2637] by the TPP Trial Defendants and various motions to exclude expert testimony by both sides, including the instant Motion. In denying the motion to decertify the TPP Trial classes, Judge Kugler found that Plaintiffs' worthlessness theory of damages – supported exclusively by Conti's testimony – was a viable economic theory supported by case law, even if it not biologically based. Decert. Op. at *5.

The trial date was postponed, and, in late March 2024, Judge Kugler ruled on a number of summary judgment motions. Critically, the Court made no findings as to "the merchantability, worthlessness, or value of the VCDs at issue." SJ Op. at *10. The Court further found that there were genuine disputes of material facts as to whether the VCDs were adulterated. *Id.* at *20. Finally, the Court determined that "[t]here is a genuine dispute of material fact as to the amount of TPPs[']damages, which centers on whether the damages are nothing because the VCDs gave the TPPs what they paid for—lowered blood pressure—or the VCDs were economically worthless and TPPs are owed the full amount they paid for the drugs." *Id.* at *37.

As noted earlier, shortly thereafter, the MDL was reassigned to the undersigned judge. In an effort to keep the case moving forward expeditiously, the TPP Trial was rescheduled to commence on October 28, 2024. Beginning on September 9, 2024, and spanning several days, the Court conducted oral argument on the parties' motions

in limine, as well as *Daubert* hearings regarding various experts' testimony, including Conti's, and an extended colloquy with counsel regarding the same. While the Court gave its rulings on many of the pending motions from the bench, it reserved on Defendants' Motion to exclude Conti's expert testimony. The parties then submitted supplemental briefing at the Court's direction [Pls.' Supp. Br. (Docket No. 2844); Defs.' Supp. Br. (Docket No. 2857); Pls.' Supp. Reply (Docket No. 2869)]. And the Court heard further argument on Defendants' Motion on October 10, 2024. [Conf. Tr. (Docket No. 2906).]

At that hearing, the Court previewed its intention to exclude Conti's testimony insofar as she opines that the VCDs are worthless and that the TPPs are therefore entitled to a full refund as damages on the breach of express warranty claim. Teva thereafter requested the opportunity to bring a motion for summary judgment on the breach of express warranty cause of action, arguing that the exclusion of Conti's testimony is fatal to that claim. [Teva Ltr. (Docket No. 2916).] Plaintiffs responded first that this Court should not exclude Conti. Second, Plaintiffs asserted that they have not limited their breach of express warranty claim to a "worthless" theory but a "worth less" theory as well. And in the event this Court disagreed, Plaintiffs requested the opportunity to amend the Complaint. [Pls.' Ltr. (Docket No. 2921).]

The Court postponed the TPP Trial once again. It had become readily apparent that the parties were like ships passing in the night, agreeing on very little about even the basics of how the trial was to proceed. The Court's intervention was needed to right the proverbial ships. This Opinion does two things. First, it lays out in necessary

detail the parameters of the damages permitted for the breach of express warranty claim. Second, guided by that framework, it addresses the Motion to preclude Conti's expert testimony.

II. THE PARAMETERS OF THE BREACH OF EXPRESS WARRANTY CLAIM AND DAMAGES

In this Court's view, the parties were preparing to try two different cases. While a trial necessarily involves differing views, the parties at the very least should agree on what they disagree about. Here, they did not. And so, before addressing the legal standards governing the admissibility of expert testimony and the Motion to preclude Conti's testimony, the Court sets forth the parameters of the breach of express warranty claim and the ways in which damages may be proven at trial. Once this framework has been clarified, the Court turns to where, if anywhere, Conti's testimony fits into the case.

A. The Scope of the Express Warranty

Disappointingly, even after the series of *Daubert* hearings and oral arguments in September 2024, the parties could not even agree on the express warranty alleged to have been breached. As a result, the Court ordered supplemental briefing to address this fundamental issue, among others. Plaintiffs contend that the "primary warranty at issue in this trial is the labeling-based representations by the Defendants that they were selling FDA approved, Orange Book A/B rated, USP compliant valsartan that was manufactured in a manner that was compliant with cGMPs and was not adulterated." [Pls.' Supp. Br. at 2.] These features, say Plaintiffs, each represent

"separate, distinct warranties that the jury may find breached." [*Id.*] Defendants counter that Judge Kugler's summary judgment ruling held only that the VCDs' label was an express warranty that that the VCDs "were equivalent to the RLD." [Defs.' Supp. Br. at 3.] According to Defendants then, "the FDA-approved label does not constitute a warranty that a prescription drug is free of nitrosamine impurities." [*Id.* at 2.]

Defendants are correct that Judge Kugler held at summary judgment that Defendants' "affirmations, statements, and labelling of their VCDs constitute express warranties that their VCDs were the equivalent to the" Reference Listed Drug. SJ Op. at *17; *see also* MTD 3 Op. at *11–12 (finding that labeling a drug as "valsartan" or "valsartan-containing" constitutes an express warranty that the drug was the "chemical equivalent of the Orange Book pharmaceutical," namely that it "was approved as a generic of the Orange Book formulation"). The Court went no further than that. Indeed, Judge Kugler went on to hold that "whether [Defendants'] labelling of the VCDs by the Orange Book designation 'valsartan' signifies [Defendants'] warranty as to the purity, identity, or any other quality of the VCDs" remained a genuinely disputed material fact precluding summary judgment. SJ. Op. at *16. Whether Defendants made any warranties as to these features specifically is therefore left for the jury to determine.

B. The Measure of Damages is the Benefit of the Bargain

Assuming the jury finds that Defendants breached an express warranty, the jury will then turn to damages. The parties agree that the correct measure of damages for the breach of express warranty claim is "the difference in value between what was bargained for and what was received," known as the benefit of the bargain theory. [Pls.' Supp. Br. at 6; Defs.' Supp. Br. at 3]; *see also Huertas v. Bayer*, 120 F.4th 1169, 1174 (3d Cir. 2024) (quoting *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Liab. Litig.*, 903 F.3d 278, 283 (3d Cir. 2018)). Beyond that, the parties do not agree.

i. A Full Refund is Not Automatic Upon a Finding of Adulteration Under the Benefit of the Bargain Theory

Time and time again, Plaintiffs have attempted to convince this Court that they are entitled to a full refund upon a mere showing of adulteration because adulterated drugs are worthless *as a matter of law*. [*See, e.g.*, Pls.' Ltr. at 8, 10 n.7, 11, 15, 17.] And time and time again, the Court has endeavored to draw out the *evidence* to support Plaintiffs' position that they are entitled to a full refund for a product that was in fact sold and used effectively for its intended purpose, but was not as expressly warranted, *i.e.*, was not cGMP compliant and uncontaminated. The commonsense approach countenanced a rule that considered the nature of the breach.

To support their position, Plaintiffs rely heavily on Judge Kugler's rulings at the pleadings stage and the Third Circuit's recent opinion in *Huertas v. Bayer*, as well as a number of other non-binding cases. It is true that Judge Kugler found that Plaintiffs' theory that the VCDs were worthless because they were adulterated, and that Plaintiffs

were therefore entitled to a full refund, "present[ed] a concrete theory of economic loss" sufficient to confer standing. MTD 2 Op. at *9. Likewise, it is true that Judge Kugler found – at the pleadings stage – that "contaminated drugs are economically worthless at the point of sale by virtue of the dangerousness caused by their contamination, regardless of whether the sold VCDs actually achieved the medical purpose of lowering blood pressure." MTD 3 Op. at *16. "Put differently, contaminated drugs, even if medically efficacious for their purpose, cannot create a benefit of the bargain because the contaminants, and their dangerous effects, were never bargained for." *Id.*

Neither of these holdings, however, go as far as Plaintiffs urge. These Opinions were issued at the pleadings stage where Plaintiffs' allegations were required to be accepted as true. We are well beyond that now. The Court is no longer concerned with what Plaintiffs have alleged, but rather with what they can *prove*.

Putting aside the procedural posture, the Court also disagrees with Plaintiffs' position that Judge Kugler's rulings mandate a full refund as a matter of law once adulteration or contamination has been established. A close read of Judge Kugler's ruling demonstrates that it is the *danger* caused by the contamination – not the contamination itself – that may result in the drug being worthless. MTD 3 Op. at *16. The fact of contamination or adulteration alone says nothing about *danger*. Instead, determining the danger caused by contamination involves evidence of risk and causation. At summary judgment, Judge Kugler left the question of damages for the jury to decide. SJ Op. at 37.

On November 7, 2024, the Third Circuit issued its precedential opinion in *Huertas v. Bayer*, 120 F.4th 1169 (3d Cir. 2024). Plaintiffs claimed victory, arguing to this Court that *Huertas* held that adulterated drugs are worthless as a matter of law. [Pls.' Ltr. at 8, 10, 15.] According to Plaintiffs, under *Huertas*, "if the jury determines that Defendants' products were adulterated, that legal prohibition renders the products economically worthless as a matter of law." [*Id.* at 15.]

First, the Court disagrees with Plaintiffs' contention that "*Huertas* is on all-fours with this litigation in nearly every important factual and legal respect." [*Id.* at 7.] Just like Judge Kugler's opinion addressed above and like many of the other cases Plaintiffs cite, *Huertas* involved a motion to dismiss for lack of standing. Given that procedural posture, the court accepted all well-pled allegations as true. *Huertas*, 120 F.4th at 1172 n.2, 1178. Likewise, the court's main inquiry was whether the plaintiffs had standing to bring their economic loss claims, *i.e.*, whether the plaintiffs had alleged an injury-in-fact. *See id.* at 1174–75. As this Court has repeatedly stated, we are well past this stage. Plaintiffs' allegations are no longer accepted as true; instead, they must be backed up by admissible evidence.

Second, the *Huertas* opinion unequivocally did not hold that that adulterated or contaminated drugs are worthless as a matter of law.[5] To claim otherwise distorts and

[5] If this were the case and "a finding of adulteration [were] legally dispositive as to economic worthlessness," as Plaintiffs contend [Pls.' Ltr. at 10], surely there would be no need to proffer Conti as an expert witness to opine that that the VCDs were worthless, and the Court would not need to resolve the instant motion.

mischaracterizes the opinion. Rather, the *Huertas* court held that the plaintiffs had plausibly alleged that the contaminated products in question – which the plaintiffs alleged were unusable and worthless – were "worth less than the product when properly manufactured." *Id.* at 1175. This was sufficient to establish an injury-in-fact and standing, so the court went no further. Indeed, the court expressly did "not decide whether contaminated products are necessarily 'worthless,' as Plaintiffs allege. Having concluded that Plaintiffs' theory is viable, *[the court] need not determine how much less contaminated products are worth*." *Id.* at 1175 n.9 (emphasis added).[6]

Plaintiffs also rely heavily on the Eleventh Circuit's decision in *Debernardis v. IQ Formulations, LLC*, 942 F.3d 1076 (11th Cir. 2019), which Plaintiffs claim the Third Circuit adopted in *Huertas*. The Court also finds *Debernardis* to be distinguishable. Like *Huertas* and unlike the instant case, *Debernardis* addressed simply whether the plaintiffs

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[6] Additionally, *Huertas* is factually dissimilar from the case at bar. For one, the *Huertas* plaintiffs all purchased the products in question during the recall period. What's more, *Huertas* explained that "if a product contains a manufacturing flaw so severe that *it cannot be used*, it is not worth the full price purchasers paid *with the understanding they would be able to use all of the product*." *Id.* at 1175 (emphasis added). The recall directed consumers to stop using the recalled products. *Id.* The *Huertas* plaintiffs alleged they "still had a portion" of the affected products that they were unable to use in light of the recall. *Id.* at 1176 n.11. In the instant case, however, the VCDs were already "entirely consumed" and "functioned for [Plaintiffs] as expected," as in the Third Circuit's *J&J* decision. *Id.* at 1176 (citing *Johnson & Johnson*, 903 F.3d at 280). And, to the extent patients had left over VCDs, the FDA directed those patients to continue taking the VCDs even after the recall because of the more immediate risks associated with unmanaged high blood pressure. [Compl. ¶ 425.]

had alleged an injury-in-fact to establish standing at the pleadings stage. *Id.* at 1080.[7] Its holding is expressly limited to this procedural posture: "we accept, *at least at the motion to dismiss stage*, that a dietary supplement that is deemed adulterated and cannot lawfully be sold has no value." *Id.* at 1085 (emphasis added).

What's more, the products at issue in *Debernardis* were alleged to have been unlawfully sold *at the outset*: the defendants knowingly[8] included a "new dietary ingredient" in the supplements without the FDA's consent, meaning they were in fact unlawful to sell at the time they were sold based on the facts known at that time. *See id.*[9] As the Court will elaborate on herein, this is a critical distinction. So critical is this distinction that the *Debernardis* court expressly cautioned that its "decision is limited to the specific facts alleged in this case." *Id.* at 1088. The court continued: "Nor are we addressing whether a plaintiff would have standing if she allegedly purchased a product that lawfully could be sold but came with inadequate warnings, or a product that was lawfully sold at the time of purchase but whose sale later was

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[7] The bulk of the cases cited by Plaintiffs are likewise distinguishable based on the procedural posture. *See, e.g.*, *Franz v. Beiersdorf, Inc.*, 745 F. App'x 47 (9th Cir. 2018) (motion to dismiss for lack of standing); *In re Aqua Dots Prods. Liab. Litig.*, 654 F.3d 748 (7th Cir. 2011) (motion for certification challenged for lack of standing); *Yachera v. Westminster Pharms., LLC*, 477 F. Supp. 3d 1251 (M.D. Fla. 2020) (motion to dismiss for lack of standing).

[8] Indeed, all claims in *Debernardis* involved allegations of culpable conduct and scienter. 942 F.3d at 1082. No breach of express warranty claim was asserted.

[9] The same is true of *Franz*, which both the Plaintiffs and *Debernardis* reference. There, the product at issue was alleged to have been unlawfully sold from the outset because it had never been approved by the FDA. *Franz*, 745 F. App'x at 48–49.

prohibited." *Id.* at 1088 n.8 (internal citations omitted); *see also In re Zantac (Ranitidine) Prod. Liab. Litig.*, No. 20-MD-2924, 2023 WL 4765409, at *2 (S.D. Fla. July 26, 2023) (distinguishing *Debernardis* because the supplements were illegal to sell at the time they were sold, whereas "in this MDL, ranitidine was legal to sell and the FDA never instructed the Defendants to stop selling ranitidine before the FDA requested that the Defendants voluntarily recall the drug.").

In sum, full refund damages are not automatically available to Plaintiffs *as a matter of law* upon a finding of adulteration or contamination. Facts matter, and Plaintiffs who have survived challenges at the pleadings stage must then *prove* their damages. There is neither space for hindsight nor room for a counter-factual world. To be clear, a full refund may be awarded in certain cases. But is *this case* one of them?

C. Proving Damages Under Benefit of the Bargain Theory

In order for the jury to answer this question at trial, the Court addresses the various ways in which a plaintiff may *prove* its damages stemming from a breach of express warranty, guided by the Third Circuit's recent decision in *Huertas*. The Court reiterates this important principle: it is one thing to allege damages and it is another thing to prove damages. A court must be mindful that the jury is instructed properly on how to determine damages in the case before it. From the Court's review of the applicable case law, there are three ways in which this measure of damages can be

established in the context of the sale and purchase of contaminated or otherwise defective products.[10] Which way should the jury follow here?

i. Defect Resulted in Product Not Performing as Intended

First, a plaintiff may establish that the product did not perform or function as intended. This is a viable route in the case of a sugar pill or placebo, for example. Where the evidence shows that a product does nothing at all, that product has no value whatsoever and a full refund would be appropriate. *See, e.g.*, *Collins v. Quincy Bioscience, LLC*, No. 19-CV-22864, 2020 WL 3268340, at *29 (S.D. Fla. Mar. 19, 2020) ("The full-refund damages model is also appropriate because consumers have no reason to purchase [product] except for its misrepresented benefit. . . . if [product] cannot affect the brain as a matter of body chemistry, then any purported benefit would be the result of the placebo effect."); *Korolshteyn v. Costco Wholesale Corp.*, No. 3:15-CV-709-CAB-RBB, 2017 WL 1020391, at *7 (S.D. Cal. Mar. 16, 2017) ("If Plaintiff can prove that [product] does not have any impact on brain health or memory and therefore does not perform as advertised on the labels and is worthless, the putative class will be entitled to restitution of the full amount they paid for the product."); *Barrera v. Pharmavite, LLC*,

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[10] In response to the Court's request and given the multitude of state law claims at issue in the MDL, the parties addressed whether the measure of damages varied across state laws. [*See* Pls.' Supp. Br. at 3–4, App.; Defs.' Supp. Br. at 3–11, App. B.] While the particulars of each state's express warranty law may differ, all apply a benefit of the bargain standard for ascertaining damages. Plaintiffs have been caught in their own trap. While they have managed to *allege* full refund damages, determining how to *prove* those damages has snared them. Plaintiffs simply say that they will prove the VCDs are worthless because they should not have been sold. But, as discussed, this ignores the proffered evidence and injects the crutch of inadmissible hindsight.

No. CV11-4153-CAS(AGRX), 2016 WL 11758373, at *10 (C.D. Cal. June 2, 2016) (full refund damages model appropriate where products alleged to be "worthless and no better than a sugar pill."); *Mullins v. Direct Digital, LLC*, No. 13 CV 1829, 2014 WL 5461903, at *3 (N.D. Ill. Sept. 30, 2014), *aff'd*, 795 F.3d 654 (7th Cir. 2015) (full refund damages appropriate where product "does not perform as advertised" and "was no more effective than [a] placebo"); *Rikos v. Procter & Gamble Co.*, No. 1:11-CV-226, 2014 WL 11370455, at *13 (S.D. Ohio June 19, 2014), *aff'd*, 799 F.3d 497 (6th Cir. 2015) ("It is a capsule filled with bacteria and inert ingredients. **If, as alleged, the bacteria does nothing, then the capsule is worthless** . . . .") (emphasis in original).[11]

Here, there is no allegation, let alone evidence proffered, that the VCDs did not perform exactly as expected for the intended purpose of lowering blood pressure. To the contrary, the evidence suggests the VCDs worked as intended and that the FDA instructed patients to continue using the VCDs due to the high risks associated with uncontrolled high blood pressure. [Compl. ¶ 425]. This theory of damages is clearly inapplicable to the facts of this case.

ii. Defect Rendered Product Unusable or Wasted

Next, a plaintiff can establish damages stemming from a breach of warranty where there the defect renders the product unusable or wasted. As the Third Circuit

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[11] Where performance is diminished or altered in some way, rather than eliminated entirely, a refund – but perhaps less than a full refund – may also be appropriate. *See Yachera*, 477 F. Supp. 3d at 1263 (plaintiffs suffered economic injury when they purchased thyroid medication with incorrect active pharmaceutical ingredient dosage).

explained recently, "if a product contains a manufacturing flaw so severe that *it cannot be used*, it is not worth the full price paid with the understanding they would be able to use all of the product." *Huertas*, 120 F.4th at 1175 (emphasis added).

In *Huertas*, Bayer issued a voluntarily recall notice in October 2021 recalling its antifungal spray products distributed between September 2018 and September 2021 due to contamination with benzene. *Id.* at 1172. The recall notice directed consumers to "stop using" and "discard . . . appropriately" the recalled products. *Id.* at 1178. Each of the plaintiffs alleged that he or she had purchased the affected products during that recall period and "still had a portion" of the recalled products that had not yet been used and could not be used because of the recall and contamination. *Id.* at 1173, 1176 n.11. In light of these facts, the *Huertas* court found that the plaintiffs had suffered an economic injury because the contamination rendered the products they had purchased – and had not yet used – unusable. *Id.* at 1175–76.

Similarly, in *Cottrell v. Alcon Laboratories*, the Third Circuit examined allegations that the bottles for certain prescription eye drops produced drops that were over twice the volume an eye could hold and therefore resulted in much of the eye drops being wasted and impossible to use. 874 F.3d 154, 159–60 (3d Cir. 2017). The court found that plaintiffs' alleged damages equaled "the cost of 'wasted' medication that Plaintiffs allege they were compelled to purchase but could not use." *Id.* at 168.

Here, however, Plaintiffs' claims relate only to *already consumed* VCDs. Thus, it cannot be argued or proven that the drugs were unusable due to their alleged

contamination or adulteration; they were already used. To the extent that any Plaintiffs had left over VCDs that they intended to use, those, too, were not wasted or unusable as it appears the undisputed evidence will be that the FDA instructed patients to continue taking the VCDs to avoid the dangers of uncontrolled high blood pressure. This theory of damages is likewise inapplicable to this case.[12]

iii. Defect is So Fundamental as to Render Product Valueless

Finally, as recognized in *Huertas* and *Debernardis*, some flaws or defects in a product are so fundamental that the product is rendered valueless. *Huertas*, 120 F.4th at 1177 (a "well-established benefit-of-the-bargain theory of contract damages" states that "some defects so fundamentally affect the intended use of a product as to render it valueless.") (quoting *Debernardis*, 942 F.3d at 1085); *see also In re Recalled Abbott Infant Formula Prods. Liab. Litig.*, 97 F.4th 525, 530 (7th Cir. 2024) ("A universal defect inherent in a product—such as a design defect or a fundamental flaw—renders each product valueless to each plaintiff . . . ."). The Court reiterates the important point that the mere fact of contamination or adulteration does not on its own mandate a finding that the defect is so fundamental as to render a product valueless as a matter of law. *Huertas*, 120 F.4th at 1175 n.9; *accord* SJ Op. at 37 (finding that question of

[12] Of course, if one of Plaintiffs' theories is that, despite the FDA's go-ahead, patients did not take the VCDs and there was waste, that would permissibly support this theory of damages. The Court, however, does not understand this to be Plaintiffs' claim for damages.

whether adulteration rendered VCDs worthless involved genuine disputes of material fact that must be decided by jury).

Instead, determining whether a flaw is so fundamental that it renders a product worthless requires an evaluation of the nature of that flaw. *See Debernardis*, 942 F.3d at 1090 (Sutton, J., concurring). As the concurrence in *Debernardis* makes clear, establishing an injury in fact sufficient to establish standing is one thing, but *proving* that injury with evidence is a whole other beast. "At summary judgment" and certainly at trial, "each claimant will need evidence to back the point up. Why was the product worthless to each of them? How did it deliver less than expected?" *Id.*

This is the only viable theory of damages upon which Plaintiffs may hang their breach of express warranty hat. Plaintiffs alleged – and Judge Kugler accepted as true at the pleadings stage – that "contaminated drugs are economically worthless at the point of sale by virtue of the dangerousness caused by their contamination, regardless of whether the sold VCDs actually achieved the medical purpose of lowering blood pressure." MTD 3 Op. at *16. Plaintiffs will now be put to their proofs.[13]

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[13] The parties should heed the useful reminder set forth in the *Debernardis* concurrence, 942 F.3d at 1090 (Sutton, J., concurring):

> At the next stages of the case, it's also a good idea to keep in mind the easy-to-miss distinctions between (1) injury in fact (a constitutional imperative), (2) statutory injury (an element of the plaintiff's cause of action), and (3) damages (a remedies calculation). Nothing guarantees that the Article III injury that gets Debernardis and Damore in the courthouse door is compensable under their legal theory or, if it is, that a jury will agree that the supplements they bought were worthless as opposed to worth less than the full purchase price.

There is no case law or other evidence to suggest that this is a purely economic question. Indeed, as will be discussed herein, Conti provides no basis for that position and the case law suggests that in fact the contrary is true. *See Zantac*, 2023 WL 4765409, at *6 (without evidence that NDMA "significantly increased risk of cancer," claim that adulterated drugs were worthless failed); *id.* at *14 ("presence of trace amounts of NDMA unconnected to evidence of human harm" is "precisely the sort of buyer's remorse case that federal courts dismiss for lack of standing.").

This entire litigation is about the alleged contamination of lifesaving VCDs with cancer-causing nitrosamines. To try this case without evidence of cancer causation is to ignore the elephant in the room. Causation must be front and center. As a result, not only will the Court permit the parties to present evidence regarding the nitrosamines in question and cancer causation, but it will require it.[14]

Plaintiffs will have the opportunity to present evidence showing the nature and extent of the risks associated with nitrosamine exposure at the levels found in the VCDs. And Defendants will counter with evidence that those risks are minimal or outweighed by the continued therapeutic value of the VCDs. The jury will then weigh

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[14] To be sure, *Huertas* made clear that "the economic injury addressed here is not for costs associated with adverse health consequences." 120 F.4th at 1177 n.14. Contrary to Plaintiffs' position, however, this does not mean that "evidence relating to general causation is not relevant in the context of these class economic loss claims." [Pls.' Ltr. at 28.] Plaintiffs continue: "[i]t is the risk that matters in this context, not actual causation of cancer." [*Id.*] But this begs the question: *risk of what?* Developing cancer. So, while evidence of general causation in the TPP Trial cannot be used to establish that any particular individual actually got cancer, it is directly relevant to the *risk* presented by the allegedly contaminated VCDs.

the evidence of these risks and dangers against the evidence of the benefits conferred to determine the value of the VCDs received (*i.e.*, the "benefit of the bargain"). A jury may very well find that a full refund is appropriate, reasoning perhaps that the risk of cancer causation was so high that it nullified any residual therapeutic value or that even a small risk was unacceptable. On the other hand, the jury may find that any increased risk of cancer was so negligible, attenuated, or insufficiently established through evidence that damages fall far short of a full refund.

Having set forth this framework, the Court now turns to Defendants' *Daubert* motion to preclude Conti's expert testimony.

III. LEGAL STANDARDS GOVERNING THE ADMISSIBILITY OF EXPERT TESTIMONY

Federal Rule of Evidence 702 governs the admissibility of expert testimony, permitting a witness "qualified as an expert by knowledge, skill, experience, training, or education" to testify in the form of an opinion, provided that "the proponent demonstrates to the court that it is more likely than not that:"

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert's opinion reflects a reliable application of the principles and methods to the facts of the case.

FED. R. EVID. 702;[15] *see also Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993). The party that proffers the expert testimony bears the burden of establishing its admissibility by a preponderance of the evidence. *Daubert*, 509 U.S. at 592 n.10 (citing *Bourjaily v. United States*, 483 U.S. 171, 175–76 (1987)).

Because Rule 702 "clearly contemplates some degree of regulation of the subjects and theories" to which an expert may testify, the Supreme Court has stated:

> [I]n order to qualify as "scientific knowledge," an inference or assertion must be derived by the scientific method. Proposed testimony must be supported by appropriate validation—i.e., "good grounds" based on what is known. In short, the requirement that an expert's testimony pertain to "scientific knowledge" establishes a standard of evidentiary reliability.

Id. at 590; *see also Oddi v. Ford Motor Co.*, 234 F.3d 136, 144–45 (3d Cir. 2000). The Court must act as a "gatekeeper" to prevent expert testimony running afoul of Rule 702 from ever reaching the jury. *See Daubert*, 509 U.S. at 596–97; *see also Cohen v. Cohen*, 125 F.4th 454, 460 (3d Cir. 2025) ("District courts are tasked with a 'rigorous gatekeeping function'") (quoting *Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000)). "This gatekeeping function is necessarily 'flexible,' granting district courts 'latitude in deciding *how*' these requirements are met." *Cohen*, 125 F.4th at 460 (internal citations omitted). "But this leeway 'is not discretion to abandon the

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[15] The Court applies the current version of Rule 702, which was amended effective December 1, 2023. The amendment does not substantively alter Rule 702, but rather "clarifies that the preponderance standard applies to the three reliability-based requirements added in 2000—requirements that many courts have incorrectly determined to be governed by the more permissive Rule 104(b) standard." FED. R. EVID. 702, advisory committee's note to 2023 amendments.

gatekeeping function' or 'perform the function inadequately.'" *Id.* (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 158–59 (1999) (Scalia, J., concurring)).

Thus, the court "must determine . . . whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue." *Daubert*, 509 U.S. at 592. "This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." *Id.* at 592–93. The Third Circuit has described Rule 702 as embodying a "trilogy of restrictions on expert testimony: [1] qualification, [2] reliability, and [3] fit." *Calhoun v. Yamaha Motor Corp., U.S.A.*, 350 F.3d 316, 321 (3d Cir. 2003) (quoting *Schneider v. Fried*, 320 F.3d 396, 405 (3d Cir. 2003)); *see also Cohen*, 125 F.4th at 460.

First, the witness must be qualified to testify as an expert, which requires "that the witness possess specialized expertise." *Calhoun*, 350 F.3d at 321. This requirement, however, has been interpreted liberally to encompass "a broad range of knowledge, skills, and training." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741 (3d Cir. 1994).

Second, the testimony must be reliable, which demands that "the expert's opinion must be based upon the 'methods and procedures of science,' rather than on 'subjective belief or unsupported speculation.'" *Calhoun*, 350 F.3d at 321 (quoting *Paoli*, 35 F.3d at 742). In other words, the Court must ensure that the evidence

adduced is scientifically valid. *Daubert*, 509 U.S. at 590. In determining the reliability of expert testimony, the Court is guided by the following factors:

> (1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put.

Calhoun, 350 F.3d at 321 (quoting *Paoli*, 35 F.3d at 742 n.8). The Court is not restricted to any "definitive checklist or test." *Daubert*, 509 U.S. at 593. This inquiry is "a flexible one" focusing "solely on the principles and methodology, not on the conclusions that they generate." *Id.* at 595.

While reliability does not require "correctness," it does prohibit "too great a gap between the data and the [expert's] opinion proffered." *Oddi*, 234 F.3d at 146 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). Thus, the court "must examine the expert's conclusions in order to determine whether they could reliably flow from the facts known to the expert and the methodology used." *Id.* (quoting *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 153 (3d Cir. 1999)).

Third, the expert's testimony must "fit" the case. *Daubert*, 509 U.S. at 592. Otherwise known as the "helpfulness" standard, this requires there to be "a valid scientific connection to the pertinent inquiry as a precondition to admissibility." *Id.* at 591–92. The fit requirement "goes primarily to relevance." *Id.* at 591. "[T]he expert's testimony must be relevant for the purposes of the case and must assist the

trier of fact." *Schneider*, 320 F.3d at 404 (citations omitted); *United States v. Zimmerman*, 277 F.3d 426, 433 n.4 (3d Cir. 2002) ("It is well-established that an expert opinion must be tailored to the specific facts of the case to have any value."). While not a high bar, the standard is "higher than bare relevance." *United States v. Ford*, 481 F.3d 215, 220 n.6 (3d Cir. 2007) (quoting *Paoli*, 35 F.3d at 745).

IV. MOTION TO EXCLUDE CONTI'S TESTIMONY

Cognizant of the foregoing principles and within the parameters set forth above, the Court now considers Defendants' challenges to Conti's expert testimony. In their papers, Defendants contend that Conti's opinion should be excluded for at least three separate reasons. First, Conti's opinions do not fit the facts of the TPP Trial because Conti purports to calculate damages based on the "point of sale" where each prescription was filled, but the subclass definitions point to the state where each TPP "paid any amount of money" for the VCDs. [Defs.' Br. at 13–16.] Because TPPs pay for VCDs through an intermediary such as a pharmacy benefits manager, and not at the point of sale, Conti's model does not calculate damages fitting the subclass definitions and instead necessarily includes recoveries for TPPs that paid for VCDs outside of the subclass states and whose claims are governed by other states' laws. [*Id.*]

Next, Defendants claim that Conti's damages calculations – which are based either wholly or in part on IQVIA Xponent data that Conti concedes are merely a "best estimate of both quantities and of transactions" and do not account for various offsets under Medicare Part D – are separately unreliable. [*Id.* at 21–31.]

Finally, Defendants argue that the lynchpin of Plaintiffs' case – namely Conti's opinion that the VCDs were worthless – has no economic or scientific basis and Conti's testimony is therefore unreliable. Through its lengthy colloquy with the parties, the Court unpacked the parties' arguments and positions. It became apparent that Defendants challenge this "lynchpin" not only on its reliability but its fit as well. Defendants contend that Conti's testimony relies upon "sophomoric economics" and improperly fails to account for the facts of the case, including residual therapeutic value and actual risk of cancer causation, as well as the fact that the VCDs were in fact lawfully sold to Plaintiffs.

In exercising its gatekeeping function, the Court focuses its greatest attention on Conti's overarching testimony and opinion that the VCDs are worthless, *i.e.*, have no value, because they were adulterated.[16] To that end, this Court conducted a *Daubert* hearing on September 9, 2024. It involved the direct and cross-examination testimony of Conti, as well as an extensive discussion between the Court and counsel. What became clearer to the Court was what exactly Conti intended to testify to. What was far less clear – and what this Court now clears up in this Opinion – is why such testimony should even be permitted. It should not – at least not at this stage of the proceedings.

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[16] As this testimony as a whole will be excluded as unreliable and unhelpful in light of the facts of this case, the Court does not delve into Defendants' more granular arguments at this time.

A. Conti's Testimony and Worthlessness Opinion

The Court begins with an overview of Conti's qualifications and testimony. Conti received a Ph.D. in Health Policy (Economics Track) from Harvard University. [Conti Decl.[17] ¶ 17.] Conti is currently an Associate Professor of Markets, Public Policy and Law in the Questrom School of Business at Boston University, where she teaches courses on the economics of the medical care industry. Her research focuses on the economics of the healthcare industry and the markets for pharmaceutical drugs in particular. [*Id.* ¶¶ 12–14.] She also serves as a consultant through Greylock McKinnon Associates, a consulting and litigation support firm. [*Id.* ¶ 12.] She has over one hundred research publications in peer-reviewed health economics and policy journals. [*Id.* ¶ 15.] Conti has submitted expert testimony as an expert in health policy and health economics in multiple legal proceedings.[18] [*Id.* ¶ 16.] Conti has testified before various government agencies, including the FDA, and has served as a consultant to the FDA's Office of Generic Drugs on issues related to drug quality and adequacy of supply. [*Id.*] In short, she is eminently credentialed. Defendants do not dispute her qualifications.

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[17] "Conti Decl." refers to the November 10, 2021 Expert Declaration of Rena Conti, Ph.D. served in this MDL, which is attached as Exhibit 2 to the Certification of Jessica Davidson ("Davidson Cert.") [Docket No. 2633-3] in support of Defendants' Motion to Exclude the Opinions of Dr. Rena Conti and has been filed under seal pursuant to the applicable Protective Order.

[18] The Court observes that the bulk of these proceedings relate to delayed generic entry or off-label marketing. [*Id.* ¶ 16 n.10, n. 11.] Only one proceeding involved cGMP violations. [*Id.* ¶ 16 n.13.]

Conti's testimony principally addresses the economic value of the VCDs in this case and how to calculate the class-wide damages allegedly suffered by the TPPs for their purchases of these products. The Court focuses, as have the parties, on Conti's testimony in the context of the breach of express warranty claims.

In developing her testimony as to the value of the VCDs and, thus, the proper measure of damages to be awarded, Conti assumed that the VCDs were adulterated from day one. These were the assumptions that Conti made in arriving at her opinion:

> Q. You assumed, did you not, that the relevant sales of these VCDs occurred between January 1, 2012, and the dates of recall for each of these three defendants, July 2018 in the case of ZHP and Teva and August 2018 for Torrent; is that correct?
>
> A. That's correct.
>
> Q. Now, critically, you were asked to assume that the at-issue VCDs were contaminated with nitrosamines in a manner which rendered them adulterated, correct?
>
> A. Correct.
>
> Q. You made no independent evaluation of the liability part of this case, correct?
>
> A. Correct.

[*Daubert* Hrg. Tr. 63:12-23 (Docket No. 2841).]

With that assumption in place, Plaintiffs propose to introduce Conti as an expert to testify in essence to the following syllogism: for there to be a price associated with a drug, there must be both demand and supply for that drug, and since an adulterated drug, as defined under 21 U.S.C. § 351(a)(1), cannot be lawfully sold pursuant to 21 U.S.C. § 331, there can be no supply or demand for that drug, and, therefore, that

drug has *no* economic value. As a result, Plaintiffs paid for something that had no value and are entitled to a full refund.

At the hearing, Conti testified:

> Q. Professor, suffice to say, you familiarized yourself and worked extensively with the regulatory framework that allows generic drugs to come to market in the U.S.?
>
> A. Yes. Almost all of my work on prescription drugs has focused on competition and specifically the market for generic drugs. This, by definition, includes the regulation, the financing, and the organization of how patients get access to these drugs and how much they cost and also what are the factors that drive prescription drug companies to enter into the U.S. market and to make them.
>
> Q. Professor Conti, what then, in economic terms, is the significance of a generic drug being adulterated in coming to market?
>
> A. It goes to the foundation of the U.S. pharmaceutical industry as it currently exists. Specifically, a drug label contains the totality of the drug's quality manufacturing, its safety, its purity, and its efficacy. And it is that label that serves as an attestation that this drug is what it says it is; that it reflects, at least a hundred years, since 1906, the rules and regulations that have been put in place to protect the U.S. public from products that are -- that might be adulterated.
>
> Q. Are drugs which meet those requirements that you've just articulated, namely, the legal requirement for safety and that they have the quality, purity, identity, and strength that they're represented to possess in their approved label, are those drugs, from an economic perspective, able to be assigned a non-zero economic value by consumers and insurers alike?
>
> A. Yes.
>
> Q. Conversely, again, from an economic perspective, can drugs that are adulterated and thus fail to meet those legal requirements that we've just articulated, can they be assigned a non-zero economic value?
>
> A. No, they cannot.
>
> Q. Can you explain why that is?

> A. Sure, of course.
>
> Consumers may have demand for many things, and firms might be able to meet that demand by supplying products. But there are regulations on what firms can provide to meet consumer demand, and those regulations essentially set up a rule of road that allows for demand to be met by supply. It's only when demand is met by supply can a market price be set for the product.

[*Daubert* Hrg. Tr. 65:14-67:6.] According to Conti and Plaintiffs, no literature is required to support her opinion since it is "actually health economics 101." [Conti Dep. Tr. at 124:23-127:3.[19]] After assigning the VCDs a zero-dollar value based on their economic worthlessness, Conti then calculated aggregate damages attributable to the various classes, opining that all TPPs should receive a full refund. [Conti Decl. ¶¶ 55–79.]

During the *Daubert* hearing, the Court questioned the "fit" of Conti's testimony because the VCDs in this case were, in fact, sold from January 1, 2012 up until the date of the recall.[20] Conti's testimony made clear that she viewed the fact that the VCDs had in fact been supplied and "may [have] contain[ed] therapeutic value" to be irrelevant to her methodology and conclusions. [*Daubert* Hrg. Tr. 74:5-75:1.] After assuming that adulteration had been found as of January 1, 2012, Conti focused

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[19] "Conti Dep. Tr." refers to the transcript of Conti's February 10, 2022 deposition attached as Exhibit 5 to the Davidson Certification.

[20] Whether Defendants knowingly or fraudulently sold the VCDs as contaminated or otherwise non-cGMP compliant as alleged in Plaintiffs' other claims is a different issue not relevant to Conti's testimony as to the breach of express warranty claim and is, in any event, a jury question.

exclusively on the fact that – in hindsight – the VCDs *should not have been sold* and therefore there had never been a "legitimate supplier." [*Id.* at 74:10-11.]

B. Neither the Law of the Case Nor Precedent Requires the Court to Admit Conti's Testimony

Plaintiffs contend that this Court has already determined that Conti's expert opinion passes muster under Rule 702 and may be presented to the jury. [Pls.' Opp'n at 1.] Plaintiffs further urge this Court to follow the Eastern District of Pennsylvania decision that permitted Conti's testimony, clamoring that the case is "nearly identical to this one." [*Id.* at 22.] The Court disagrees on both fronts.

It is true that at the class certification stage, Judge Kugler denied Defendants' motions to preclude Conti's testimony.[21] "The core of Dr. Conti's worthlessness theory" in this litigation is that a drug containing any impurities—even if the purported impurity does not undermine the safety or efficacy of the medication—"can have no supply curve, and is therefore worthless." Class Cert. Op. at *49. As to Defendants' challenges to the scientific and mathematical models underpinning Conti's testimony, Judge Kugler found "Conti's methodology to have sufficient scientifically reliable underpinnings," but made "no statement here as to its legal propriety." *Id.* at *51. Defendants also challenged Conti's testimony claiming that "Conti's opinions rest on the highly flawed premise that the VCDs had no value" despite being "therapeutically effective," and that "Conti arrived at her economic theory of VCD worthlessness only

[21] The Court did not hold a *Daubert* hearing at the class certification stage.

by relying on, *ab initio*, plaintiffs' legal allegations of their worthlessness." *Id.* As to these arguments, Judge Kugler ruled that Defendants failed to "defeat plaintiffs' arguments that Dr. Conti's 'worthlessness' theory has already achieved validation in *BCBS*." *Id.* (citing *Blue Cross Blue Shield Association v. GlaxoSmithKline LLC* ("*Blue Cross II")*, No. CV 13-4663, 2019 WL 4751883 (E.D. Pa. Sept. 30, 2019).

But this was all at the class certification stage. Conti was offered at that time to establish that the economic loss damages could be assessed on a class-wide basis as required by Federal Rule of Civil Procedure 23. To be sure, Rule 702 and *Daubert* apply at the class certification stage to the extent an expert is offered to demonstrate conformity with Rule 23. *In re Insulin Pricing Litig.*, No. 217CV00699BRMRLS, 2024 WL 416500, at *9 (D.N.J. Feb. 5, 2024) (citing *In re Blood Reagents Antitrust Litig.*, 783 F.3d 183, 187 (3d Cir. 2015)). As Judge Kugler recognized, however, "[a]t [the] class certification stage, the methodology of an expert need not be perfect or even legally correct." Class Cert. Op. at *51. The Court reasoned that "[t]o the extent that there is disagreement over the models . . . that question is best answered by a jury;" in other words, Judge Kugler determined that Defendants' challenges implicated the weight, rather than the admissibility, of Conti's fundamental opinion. *Id.* at *51 n.13.

This litigation has advanced considerably since class certification. It is now beyond the realm of allegations, theories, and arguments; it is in the world of proof and evidence. As such, Conti's testimony is now no longer offered just to establish an ascertainable class-wide theory of damages, but as competent evidence of actual damages sustained by the Plaintiffs.

What's more, Rule 702 has since been amended to clarify the rigorous and essential gatekeeping function that is required of district courts. While the December 2023 Amendments did not materially alter the admissibility requirements for expert testimony, they "emphasiz[ed] the preponderance standard in Rule 702 [which] specifically was made necessary by the courts that have failed to apply correctly the reliability requirements of that rule." FED. R. EVID. 702, advisory committee's note to 2023 amendments. Rule 702(d), as amended, requires that "the expert's opinion reflects a reliable application of the principles and methods to the facts of the case."[22] The amendment was intended to "emphasize that each expert opinion must stay within the bounds of what can be concluded from a reliable application of the expert's basis and methodology." *Id.* The advisory committee's note continues: "Judicial gatekeeping is essential because just as jurors may be unable, due to lack of specialized knowledge, to evaluate meaningfully the reliability of scientific and other methods underlying expert opinion, jurors may also lack the specialized knowledge to determine whether the conclusions of an expert go beyond what the expert's basis and methodology may reliably support." *Id.* The Third Circuit has also recently reemphasized the district court's "rigorous gatekeeping function." *Cohen*, 125 F.4th at 460–61.

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[22] The prior version of Rule 702(d) required that "the expert has reliably applied the principles and methods to the facts of the case."

The Court has "an ongoing obligation to act as a 'gatekeeper' with regard to scientific opinion evidence throughout a trial." *Lithuanian Com. Corp. v. Sara Lee Hosiery*, 202 F. Supp. 2d 371, 376 (D.N.J. 2002) (citing *Kumho*, 526 U.S. at 152; *Daubert*, 509 U.S. at 592). This Opinion is an exercise of that continuing duty. At this advanced stage in the litigation and in light of the amendments to Rule 702, the Court must determine whether Plaintiffs have established – by a preponderance of the evidence – that Conti's opinion does *actually* (not just may) reflect a reliable application of reliable principles and methods to the facts of the case. *See* FED. R. EVID. 702(d). For the reasons set forth herein, the Court finds they have not.

The Court would be remiss not to address the *Blue Cross* court's "validation" of Conti's worthlessness theory. At class certification, the Court was persuaded by the *Blue Cross* court's reasoning and acceptance of Conti's testimony. Class Cert. Op. at *51 (citing *Blue Cross II*, 2019 WL 4751883, at *8–9). At this stage, however, the Court is no longer persuaded.[23] Given the development of the factual record since class certification – in particular the clarification as to the value of the VCDs pre-recall versus post-recall – the distinctions between this case and *Blue Cross* are now glaring.

In *Blue Cross*, 38 private health insurance companies sought full refunds for purchases made between 2000 and 2005 of 17 at-issue drugs that were manufactured in a particular plant rife with cGMP violations. *Blue Cross Blue Shield Ass'n. v.*

[23] It goes without saying that *Blue Cross* – a decision rendered by the District Court for the Eastern District of Pennsylvania – is not binding upon this Court.

GlaxoSmithKline LLC ("*Blue Cross I*"), 417 F. Supp. 3d 531, 537–43 (E.D. Pa. 2019). Having been manufactured in a cGMP non-compliant manner, the *Blue Cross* plaintiffs claimed the adulterated drugs were worthless and offered Conti as an expert to testify as to her worthlessness theory supported by basic supply and demand economic principles. *Blue Cross II*, 2019 WL 4751883, at *2.

As Defendants' rightly point out, however, "[i]n *Blue Cross*, unlike this litigation, the FDA made a formal finding that the drugs at issue were 'adulterated within the meaning of' the FDCA while they were ***still being sold and paid for*** by class members." [Defs.' Supp. Br. at 11 (citing *Blue Cross I*, 417 F. Supp. 3d at 541) (emphasis in original).] Indeed, during the relevant period, the FDA inspected the plant in question nine times to check for cGMP violations, ultimately issuing over a handful of Form 483 notices, indicating "significant objectionable condition[s] relating to products and/or processes, or other violations of the [FDCA]." *Blue Cross I*, 417 F. Supp. 3d at 538, 541–42. In July 2002, the FDA issued a warning letter deeming certain of the at-issue drugs cGMP non-compliant and adulterated. *Id.* at 541. After a quality assurance manager disclosed "serious quality assurance and compliance problems" at the plant to the FDA, a criminal investigation was commenced in 2003, which resulted in a guilty plea and a $140 million criminal penalty. *Id.* at 541, 548.

All of this is to say that cGMP non-compliance and adulteration were well known throughout the time period the *Blue Cross* plaintiffs paid for the at-issue drugs.

Those drugs should not have been sold *at the time they were sold*. There was no need for Conti to create a counter-factual world or speculate on what would have happened had the parties and the FDA known of the cGMP violations at the time. In other words, Conti's testimony fit there. But, as will be described in detail below, these are not the facts of this case. Conti's testimony does not fit *here*. Having found that Conti's testimony has not "already achieved validation" under the facts and posture of this case, the Court now turns to its analyses of relevance and reliability.

C. Conti's Testimony Ignores the Real World and is Not Helpful to the Jury

Conti's opinion, perhaps relying too heavily on Judge Kugler's earlier decisions,[24] ignores the "real world" of what happened in this case. Simply put, the problem with Conti's testimony is that it does not fit the facts here – at least with respect to the breach of express warranty cause of action. An expert's testimony "fits" the proceedings only if it will help the trier of fact to understand the evidence or determine a fact in issue. FED. R. EVID. 702(a); *Cohen*, 125 F.4th at 464. For purposes of this case, Conti's testimony is not helpful.

Conti readily opined there was no legitimate supplier for the adulterated VCDs and therefore the VCDs had no economic value from the day the VCDs were first sold. [*Daubert* Hrg. Tr. 74:10-11.] Conti's conclusion rests solely on the fact that it was

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[24] By the same degree, Defendants, too, may have put too much emphasis on this Court's prior ruling. This Court's analysis of Conti's testimony is a far more straightforward one: Conti ignores the facts of this case, that is, that these drugs were, in fact, sold and did, in fact, provide a therapeutic value. Plaintiffs do not dispute these two basic facts.

"impermissible" to have sold the VCDs. Because it was impermissible – *in hindsight* – the value of the VCDs is zero and the Plaintiffs should receive a full refund. These are neither the facts of the case nor an adequate statement of the law as to damages in a breach of express warranty case.

Conti then seemingly contradicted herself. After testifying that the adulterated VCDs were worthless because there was no legitimate supply for the drugs, she later testified that the VCDs do in fact have economic value up until the time the FDA shuts down the market:

> CHIEF JUDGE BUMB: So it sounds like what you're saying is unless and until the FDA declares them adulterated, they have some economic value?
>
> THE WITNESS: Unless and until -- well, it's really – it's on the manufacturer, actually, to inform the Food and Drug Administration that there has been contamination and adulteration. That's part of their obligations. And once that occurs, there's a period of determination by the regulator on whether and how to either shut down the market for these products or to allow them and under what circumstances. And indeed that is what happened in this case.
>
> CHIEF JUDGE BUMB: And up until that point, they have an economic value?
>
> THE WITNESS: Yes.

[*Daubert* Hrg. Tr. 76:3-16.] This confusion further supports this Court's conclusion that Conti's testimony would not be helpful to the jury.

The reality is that there *was in fact* a legitimate supply of FDA-approved VCDs and the VCDs were *in fact* lawfully sold from 2012 until the recalls in 2018. As the Third Circuit has explained, "ignoring 'the real world'" can "render [an expert]

opinion inadmissible." *Elcock*, 233 F.3d at 756 (cleaned up); *accord id.* at 755 n.12 (collecting cases that "have similarly excluded expert opinions not grounded in the facts of a case"); *Edison Wetlands Ass'n v. Akzo Nobel Chems., Inc.*, No. 08-419 (FSH), 2009 WL 5206280, at *6 (D.N.J. Dec. 22, 2009) (an expert's assumptions "cannot ignore the 'real world'" and expert's "conclusions of this assessment are rendered meaningless because his factual assumptions . . . are not tied to the facts in a reasonable way.").

This reality stands in stark contrast to *Blue Cross* and *Debernardis* where the products should not have been sold from the start based on the information *actually known* to the parties and the FDA at the time of sale. As explained above, the manufacturing plant where the at-issue drugs in *Blue Cross* were made was rife with cGMP violations throughout the entire relevant period and the drugs in question continued to be sold after the FDA's adulteration finding. *Blue Cross I*, 417 F. Supp. 3d at 541–43. Conti's testimony in that case fit the facts without any stretch of the imagination or speculation. Similarly, as this Court has already explained, the products in *Debernardis* were alleged to have been unlawfully sold when sold based on the facts known at that time. *See Debernardis*, 942 F.3d at 1085.[25] Those products really never should have been on the market. Again, there was no need to imagine or speculate about a counter-factual world in which the FDA had declared the drugs

[25] Notably, *Debernardis* did not involve or address expert testimony.

adulterated or otherwise cGMP non-compliant at the outset (because it had already done so).

Plaintiffs argue that Conti's testimony does not involve a "'retroactive' or hypothetical world." [Pls.' Ltr. at 21.] But it most certainly does. "In contrast" to *Debernardis* and *Blue Cross*, "in this MDL, [the VCDs were] legal to sell and the FDA never instructed the Defendants to stop selling [the VCDs] before" Defendants voluntarily recalled the drugs. *See Zantac*, 2023 WL 4765409, at *2. Plaintiffs' argument that "illegally sold products have no legitimate value" fails too for this reason. [Pls.' Supp. Reply at 1 n.1.] The VCDs were not illegally sold at the time of sale and Plaintiffs cannot reasonably argue otherwise without proving a culpable mental state, which Plaintiffs have continuously and correctly disavowed as a requirement for the breach of express warranty claim. [Pls.' Supp. Br. at 3 ("Knowledge of scienter is not an element of the warranty claim."), App. Part I (collecting cases).] The Court will not permit an expert to speculate in this way.

Plaintiffs half-heartedly attempt to recast their worthlessness theory of damages as a fundamental defect to fit the language of *Huertas*. [*See* Pls.' Ltr. at 7–9.] But Plaintiffs' only evidence to support worthlessness thus far is Conti's expert testimony. This is like trying to fit a square peg in a round hole. Economic supply curves say nothing about whether any defect in the VCDs is "fundamental." Plaintiffs yet again argue that "economic worthlessness damages are available as a matter of law because the defect at issue is fundamental." [*Id.* at 8.] And the Court yet again finds that this is *not* what *Huertas* – or any of the cases cited by Plaintiffs – held. Plaintiffs cannot

simply *assert* a fundamental flaw; they must prove it. That requires an analysis of causation and risks versus benefits. But Conti's methodology and testimony do not even account for the nature, impact, or extent of the adulteration. Her testimony is black and white: either a drug is adulterated and has no value, or it is not and has some value. This is simply not helpful to a jury in determining the value of the VCDs sold to the Plaintiffs or whether the VCDs were so fundamentally flawed so as to be rendered valueless. Without evidence of the nature of the flaw, the Court views this to be just a case of buyer's remorse. *See Zantac*, 2023 WL 4765409, at *14 ("what the Plaintiffs are left with is a buyer's remorse case" where drug performed as expected, did not cause them harm, and all that is complained of "is the presence of trace amounts of NDMA unconnected to evidence of human harm.").

All Conti adds to the equation then is that adulterated drugs *should not* be sold, or if the adulteration is known, *cannot* be sold.[26] From there, she opines that "these are manufacturers that are picking the pocket of American consumers and payors by selling products into the market that *should not have been*." [*Daubert* Hrg. Tr. 77:5-8 (emphasis added).] But this is precisely within the province of the jury: whether Defendants knew at the time the drugs were adulterated or otherwise cGMP

[26] Expert testimony is not even necessary to establish this. The plain meaning of the statute makes this clear: "The following acts and the causing thereof are prohibited: (a) The introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is adulterated or misbranded." 21 U.S.C. § 331.

non-compliant. It is also, as Plaintiffs themselves readily recognize, not relevant to their breach of express warranty claim.

"'Fit' is not always obvious, and scientific validity for one purpose is not necessarily validity for other, unrelated purposes." *Daubert*, 509 U.S. at 591. "Thus, even if an expert's proposed testimony constitutes scientific knowledge, his or her testimony will be excluded if it is not scientific knowledge for purposes of the case." *Paoli*, 35 F.3d at 743. That Conti's testimony fit the facts in *Blue Cross* has no bearing on whether it fits in this case. Conti's testimony that the VCDs here are worthless is insufficiently "tailored to the specific facts of the case to have any value." *See Zimmerman*, 277 F.3d at 433 n.4. The Court is cognizant that "expert testimony can be powerful and misleading" to a jury. *Blue Cross II*, 2019 WL 4751883, at *4 (citing *Ford*, 481 F.3d at 219 n.6). So that an expert's testimony does not improperly sway a jury, "the Third Circuit has cautioned district courts to 'tread carefully when evaluating proffered expert testimony.'" *Id.* (quoting *Ford*, 481 F.3d at 219 n.6). With both this direction and its critical gatekeeping function in mind, the Court finds that Conti's testimony that the VCDs are worthless is neither relevant nor helpful in this case and should be excluded.[27]

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[27] Only if a *jury* determines that the VCDs were worthless – based upon other competent evidence – may Conti's testimony regarding the calculation and amount of damages be permissible. In that case, Conti would be permitted to *assume* worthlessness in her calculations. The Court intends to address this, among other topics, at an upcoming conference with the parties.

D. Conti's Testimony is Unreliable and Rests Solely on Her *Ipse Dixit*

Finally, the Court turns to the reliability of Conti's testimony and methodology. As previously noted, the core of Conti's testimony is that cGMP non-compliant or adulterated drugs cannot lawfully be sold and, therefore, assuming cGMP non-compliance and adulteration, the VCDs were entirely worthless – regardless of any continuing therapeutic value provided by the VCDs and regardless of the nature of the non-compliance or adulteration. Expert testimony is reliable only if it based upon "methods and procedures of science, rather than on subjective belief or unsupported speculation." *Calhoun*, 350 F.3d at 321 (internal quotations omitted). Defendants argue that Conti's testimony is "highly subjective and lacking in scientific support." [Defs.' Br. at 20.] Plaintiffs counter that Conti's methodology is rooted in basic widely accepted economic principles, obviating the need for supporting economic literature, and that Defendants improperly challenge the correctness of her opinions, rather than her methodology. [Pls.' Opp'n at 10 n.1, 25–26.]

The Court disposes of Plaintiffs' latter argument first. While Plaintiffs are correct that challenges under *Daubert* and Rule 702 must focus "solely on the [expert's] principles and methodology, not on the conclusions that they generate," *Daubert*, 509 U.S. at 595, that does not mean that the expert's conclusions are irrelevant to the *Daubert* analysis. Indeed, courts "must examine the expert's conclusions in order to determine whether they could reliably flow from the facts known to the expert and the methodology used." *Oddi*, 234 F.3d at 146. In any event, the Court disagrees with Plaintiffs that Defendants challenge only the correctness of Conti's conclusion that the

VCDs are worthless. In this Court's view, the conclusion that adulterated drugs *may* be worthless under certain circumstances cannot be genuinely contested at this stage. Rather, it is the manner in which Conti arrives at this conclusion that the VCDs *in this case* are worthless that the Defendants attack as unfounded and unreliable. Having cleared that up, the Court turns to those attacks now.

Defendants argue that Conti's testimony is unreliable because "Conti has never cited any economic literature supporting her views about legitimate supply curves or adulterated drugs having no value; nor could she identify any such literature in her deposition." [Defs.' Br. at 4.] Instead, Conti's testimony is supported only by her own say so. The Court agrees. Plaintiffs have presented no economic literature showing that her methodology is peer reviewed, generally accepted, or used to value drugs outside the context of litigation.[28] *See Calhoun*, 350 F.3d at 321 (describing factors to be considered in determining reliability). Plaintiffs claim that no economic literature is needed because Conti's testimony derives from "health economics 101" supply and demand principles. [Pls.' Opp'n at 10 n.1.]

But this is both too simplistic and too doctrinaire. Conti provides no basis from which to find that her methodology for valuing the VCDs is reliable, accepted, or appropriate. She does not consider or evaluate the risks and benefits the VCDs

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[28] Even in litigation, this methodology does not appear to be widely accepted or utilized. Out of Conti's many expert engagements, only one other involved this type of valuation testimony – *Blue Cross* – which the Court has already found to be inapposite. And in that case, although not excluded, Conti's testimony never made it to a jury as the litigation settled prior to trial.

conferred on purchasers at the time of purchase. She does not even account for the nature of the flaw resulting in adulteration.[29] And, most critically, she does not explain why all of this is justified. Without more, her testimony that, based on "health economics 101," an adulterated drug can never have any value whatsoever is nothing more than an *ipse dixit* assertion of worthlessness. But "[n]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Joiner*, 522 U.S. at 146; *accord Player v. Motiva Enters., LLC*, 240 F. App'x 513, 520 (3d Cir. 2007) ("District Court certainly had the discretion to exclude opinion evidence that is connected to existing data only by the *ipse dixit* [or say-so] of the expert.").

The Court agrees with Defendants: Plaintiffs and Conti have "simply *asserted* a worthless product that delivered its anticipated therapeutic benefit without *proving* it." [Teva Reply Ltr. at 5 n.2 (Docket No. 2934).] Plaintiffs rely solely on Conti's *ipse dixit* and speculation, rather than scientific principles. The subjective and speculative nature of Conti's testimony was made plain at the *Daubert* hearing. Conti testified inconsistently that the adulterated VCDs were worthless from day one, but that

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[29] Taken to its logical conclusion, Conti's testimony would require a full refund for even technical or immaterial violations of cGMP. Imagine a minor cGMP violation that results in a harmless speck of flour being introduced into a product. Conti's methodology would require a full refund across the board to all purchasers. This would be patently inequitable, not to mention contrary to the law of benefit of the bargain damages as set forth above. Plaintiffs would likely agree, as they have unequivocally assured the Court that they would not bring a suit based on immaterial cGMP non-compliance because "there's no risk to health." [Conf. Tr. at 12:5-13.]

"unless and until the FDA declares them adulterated, they have some economic value." [*Daubert* Hrg. Tr. 76:3-16.] She also testified as to the policy incentives underlying her approach [*id.* at 77:5-8], elaborating on the statements in her expert report that "assigning a non-zero value" to the VCDs would be "perverse" and "incentivize and legitimize cheating and non-compliance." [Conti Decl. ¶ 45.] These are not proper bases for expert testimony. *See Calhoun*, 350 F.3d at 321.

Conti opined that the VCDs' "value" – which is the proper measurement for benefit of the bargain damages – is determined by the product's market price and nothing else. [Defs.' Br. at 4; Defs.' Reply at 3–4.] Yet this conflates value with price without justification or explanation. There is no reliable basis to presuppose, as Conti does, that the value of the VCDs as received boils down to just whether or not they could have been sold in hindsight. Even Conti admitted as much in a deposition: the "clinical benefit of a product affect[s] its economic value." [Conti Class Rep. Dep. 110:11-18.] Case law, in addition to common sense, supports a more nuanced approach that also considers the therapeutic value of the products and the nature and danger of the defect. *See, e.g.*, *In re Baycol Prods. Litig.*, 218 F.R.D. 197, 213 (D. Minn. 2003) (court "cannot accept" that recalled drug "did not provide any benefit" where it was undisputed that drug "effectively reduce[d] cholesterol."); *In re Rezulin Prods. Liab. Litig.*, 210 F.R.D. 61, 68–69 (S.D.N.Y. 2002) (presumption that drug was worthless "is not a defensible position" where drug was "enormously beneficial to many patients.").

The Court finds that Conti's testimony is unreliable in light of its inconsistencies and the stark lack of scientific or economic basis for her methodology. Conti's opinion is largely argument and advocacy based on her own *ipse dixit*, rather than a reliable application of economic principles and methods to the facts of the case. Perhaps this has all come about because of Plaintiffs' failure to appreciate the critical distinction between alleging an injury in fact for standing, sustaining an injury as an element of the claim to establish liability, and then proving the injury to calculate damages. For these reasons, the Court will not permit Conti to testify that the VCDs are worthless.

V. NEXT STEPS AND THE PENDING MOTIONS

After all this has been said and done, where do we go from here? The Court will address that question at the upcoming Case Management Conference.

In October 2024, the Court postponed the previously scheduled TPP Trial pending the resolution of the instant motion, among other issues. The Court expressed its concerns about the looming question of cancer causation and the difficulty of fairly trying this case without addressing cancer causation. After all, at its heart, the risk of cancer is what this whole case is about. To that end, the Court directed the parties to move forward in preparing individual consumer personal injury cases for bellwether trials. The parties have diligently done so. The parties are now engaging in expert discovery relating to causation and other issues. The first personal injury bellwether trial is scheduled to begin in just a matter of months. Others will be scheduled for the remainder of the calendar year.

As this Court has ruled, evidence of general causation must be presented in the TPP Trial as well. Teva has requested that the Court hold additional *Daubert* hearings on the parties' general causation experts, which are "directly relevant to the bellwether workup" and "to the economic loss tracks." [Teva Ltr. at 5–6.] Deadlines to file Rule 702 and other motions have been set forth in Judge Vanaskie's Orders establishing case management schedules for the upcoming bellwether cases. [Docket Nos. 2982, 2988.] The parties should be prepared to address whether this process suffices or whether other *Daubert* hearings addressing general causation experts are necessary for the TPP Trial specifically.

This Court has analyzed the propriety of Conti's testimony in the context of the breach of express warranty claims. The parties shall be prepared to address the implications of this Court's exclusion of Conti's worthlessness testimony on the remainder of the claims and pending motions.[30] To the extent that this Court's exclusion of Conti's worthlessness testimony impacts a pending motion, the parties shall be prepared to address that at the conference.

Finally, Teva has also requested leave to file a renewed partial summary judgment motion. According to Teva, Plaintiffs are foreclosed from arguing that the VCDs are "worth less" than bargained for because they have limited themselves instead to a theory that the VCDs are "worthless." [Teva Ltr. at 3–5.] Upon the

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[30] A number of motions *in limine* and *Daubert* motions were addressed by the Court during oral argument in July and September 2024. The parties shall submit a proposed Order for the Court's review confirming the Court's rulings on those motions.

exclusion of Conti's testimony, Teva contends, Plaintiffs have no remaining evidence from which a jury could determine this and summary judgment is appropriate. [*Id.*] Plaintiffs disagree and in turn request leave to amend the complaint "to more explicitly add a worth less theory." [Pls.' Ltr. at 23 n.19.]

In light of this Court's rulings set forth herein and the Third Circuit's decision in *Huertas*, the Court does not intend to grant either request at this time. The distinction between "worthless" and "worth less" is muddied after *Huertas*. The Third Circuit held, in sum and substance, that a product alleged to be "worthless" is necessarily also alleged to be "worth less" than bargained for. *See Huertas*, 120 F.4th at 1176 ("Plaintiffs plausibly alleged that the benzene contamination—the product's defect—rendered it unusable [*i.e.*, worthless], making it inherently worth less than if it had been manufactured properly."). As such, Plaintiffs' claim can be said to have encompassed both and the Court sees no need for Plaintiffs to amend their complaint.

Additionally, in light of this Court's decision to require general causation evidence in the TPP Trial, Teva's request to file a summary judgment motion is premature. Thus far, the parties have been laboring under the assumption that causation was not part of the TPP Trial. But going forward it will be. Plaintiffs shall have an opportunity to present evidence that the nitrosamine exposure in the VCDs may cause cancer. Defendants can, of course, rebut that evidence. What that evidence will show remains to be seen.

VI. CONCLUSION

For the foregoing reasons, Defendants' Motion to Exclude the Opinions of Dr. Rena Conti [Docket No. 2633] is **GRANTED**. Conti will not be permitted to testify that the VCDs were worthless. The Court has considered Defendants' request to file a summary judgment motion and believes any such motion would be premature at this time. The Court has also considered Plaintiffs' request to amend the complaint and finds amendment to be unnecessary. The Court shall discuss the path forward for the TPP Trial, including how the Court's exclusion of Conti's worthlessness testimony impacts any pending motions *in limine* and *Daubert* motions, with the parties at the upcoming Case Management Conference scheduled for April 28, 2025. The parties shall meet and confer in advance of the conference in an effort to find agreement where possible and streamline the disputes that will be raised with the Court.

s/Renée Marie Bumb
RENÉE MARIE BUMB
Chief United States District Judge

Dated: April 7, 2025